REMARKS

By this Amendment, independent Claim 1 has been amended in a clarifying manner to place the application in immediate condition for allowance.

In the outstanding Office Action, the Examiner rejected Claims 1, 4-7 and 9 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. In making this ground of rejection, the Examiner has stated that as Claim 1 was previously presented "technically both sides of the bag can be anion or cation since the resin placed in both sides can be one or the other." While Applicants respectfully disagree with this position as taken by the Examiner, independent Claim 1 has been amended to add the words "one of" so that the last phrase of the claim reads as follows:

> "wherein said cross-linked ion-exchange resin is one of a cation-exchange resin or an anion-exchange resin as determined by the ionic medicine to be administered."

It is respectfully submitted that the amendment makes no material change in the meaning of the claim and is merely provided to more clearly set forth that which Applicants regard as the invention. Accordingly, it is submitted that the ground of rejection under 35 U.S.C. 112, second paragraph, has been overcome.

In the outstanding Office Action, the Examiner has rejected Claims 1, 4-7 and 9 under 35 U.S.C. 103(a) in three different grounds of rejection, each relying upon the teachings of U.S.

Published Patent Application No. 2005/007084081 to Matsumura et al. as the main prior art teaching. The Examiner has rejected Claims 1 and 4-6 in reliance upon the combination of Matsumura et al. in view of U.S. Patent No. 4,713,050 to Sibalis. The Examiner has relied upon the combination of Matsumura et al., Sibalis and U.S. Patent No. 5,169,382 to Theeuwes et al. to reject Claims 7 and 9, and has relied upon the combination of Matsumura et al. and U.S. Patent No. 4,217,200 to Kedem et al. to reject Claims 1 and 4-6.

None of these grounds of rejection makes a prima facie case for obviousness as is required under the Court precedents for 35 U.S.C. 103, particularly because Matsumura et al. fail to teach that which the Examiner has represented they teach.

The present invention relates to a bag designed to administer medication which is formed by melt-adhering the peripheral edges of an anion-exchange membrane and a cation-exchange membrane. These ion-exchange membranes are made from a porous film having a porosity in the range of 25% to 95%, and the porous film is filled with a cross-linked ion-exchange resin at a filling ratio of 5% to 95%.

The cross-linked ion-exchange resin can be effectively used in an iontophoresis or a like device as the ion-exchange membrane to facilitate feeding of medication to a predetermined site or for interrupting migration of the medicine. The cross-linked

ion-exchange resin is not only stable against various solvents or medicines, but also exhibits excellent physical properties such as significant strength. However, the ion-exchange membrane using the cross-linked ion-exchange resin has pore heat-melt adhesion and cannot be used in the form of a bag. To Applicants' knowledge, the ion-exchange membrane has not previously been used in the form of a bag in the field of iontophoresis.

In accordance with the teachings of the present invention, a porous thermoplastic resin film filled with a cross-linked ion-exchange resin is employed as the ion-exchange membrane in the form of a bag, thereby facilitating preservation of the medication in a compact form.

In the present invention, the bag containing the medicine therein is formed by melt-adhering the peripheral edge portions of the anion-exchange membrane and of the cation-exchange membrane. Thus, depending upon the polarity of the ionic medicine, therefore, one of the membranes is closely adhered to the skin and, in this configuration, a predetermined voltage is applied so that the medicine is reliably prevented from migrating to the side opposite to that which is engaged to the skin and so that the medication is selectively fed to the living body through its skin.

In stark contrast to the present invention, the Matsumura et al. invention does not describe the use of an ion-exchange

membrane to hold medication. In this regard, with reference to Figures 3 and 4 of Matsumura et al., it is plain that the ion-exchange membrane is a member separate and apart from the membrane 14 to which the Examiner relies in making the ground of rejection. In accordance with the teachings of Matsumura et al., the membrane 14 that retains the medication retains it through impregnation of the medication within the walls of the membrane 14. In Matsumura et al., the structures that provide the ability for cation-exchange or anion-exchange are designated by the reference numerals 13 and 15, respectively, and are, again, separate and apart from the membrane 14 which holds the medication. In Matsumura et al., the membrane 14 is not in the form of a bag but, rather, consists of an elongated sheet-like form. Thus, the teachings of Matsumura et al. are completely different from those of the present invention.

In proposing to reject Claims 1 and 4-6 in reliance upon the combination of Matsumura et al. and Sibalis, the Examiner relies upon Sibalis for the alleged teaching of a device using medicine and which can be sealed in a bag, with reference to column 3, lines 22-41 thereof. Sibalis makes reference to the bag 24 best seen in Figure 2. In Sibalis, the bag 24 is formed using a film having voids that permit the medication to pass therethrough, but is not formed with an ion-exchange membrane. Thus, even if it were appropriate to combine Matsumura et al. and Sibalis, the

question must be asked as to what is being combined. In this regard, it is clear that what is being combined is the element 14 of Matsumura et al. and the element 24 of Sibalis. Again, the element 14 of Matsumura et al. consists of an ionic drug retaining membrane. See paragraph 0203 of Matsumura et al. In Matsumura et al, again, the ionic exchange membranes are referred to with reference numerals 13 and 15 and they are separate and apart from the ionic drug retaining membrane 14. See Matsumura et al., paragraph 0206.

Thus, in light of the teachings of Sibalis, the modification of Matsumura et al. would make the ionic drug retaining membrane 14 into a bag. However, in light of the teachings of Matsumura et al., that bag would be an ionic drug retaining membrane and not an ion-exchange membrane as recited in the claims as previously presented. Moreover, if the ionic drug retaining membrane 14 of Matsumura et al. were made into a bag, the question must be asked as to where the ion-exchange membranes 13 and 15 would then be located. Apparently, in order for the Matsumura et al. invention to operate as intended, there must be some relationship between the ionic drug retaining membrane 14 and the ion-exchange membranes 13 and 15 that allows the medication to be passed through the ion-exchange membranes 13 and 15. If one modifies Matsumura et al. in view of Sibalis to change the membrane 14 of Matsumura et al. into a bag, it is not

seen how the medication would be able to pass through the ion-exchange membranes 13 and 15.

Thus, there are two main reasons why this ground of rejection, the combination of Matsumura et al. and Sibalis, is untenable under Patent Law. First, even if these references were combinable, they would not result in arriving at the invention set forth in the claims as previously presented in which the bag is made of ion-exchange membranes. Second, the modification would destroy the Matsumura et al. device for its intended purposes because the medication would be isolated from the ion-exchange membranes.

Thus, for these reasons, it is respectfully submitted that Matsumura et al. and Sibalis are not combinable under 35 U.S.C. 103 to meet the terms of Claims 1 and 4-6.

Concerning the rejection of Claims 7 and 9 in reliance upon the combination of Matsumura et al. and Sibalis, and further in view of Theeuwes et al., it is first noted that Theeuwes et al. fail to cure the deficiencies of the combination of Matsumura et al. and Sibalis vis.a.vis Claims 1 and 4-6. Claim 7 depends from Claim 6 and Claim 9 depends from Claim 7. As such, for the same reasons set forth above with regard to Claims 1 and 4-6, Claims 7 and 9 are equally patentable.

Moreover, Theeuwes et al. disclose an iontophoresis device provided with a flexible bag 38 containing a medicine. In a

similar fashion to Sibalis, the flexible bag 38 of Theeuwes et al. is not formed out of an ion-exchange membrane. This is clear from the fact that the Theeuwes et al. device ion-exchange membrane 30 is provided on the side where the flexible bag 38 comes into contact with the living body. Thus, in the same manner as is the case with Sibalis, the resulting combination does not provide an ion-exchange membrane in the form of a bag storing a medication for dispensing through the skin of a living body.

The Examiner has rejected Claims 1 and 4-6 in reliance upon the combination of Matsumura et al. and Kedem et al. In making this ground of rejection, the Examiner has relied upon Matsumura et al. in the same way as described above with regard to the earlier rejection of Claims 1 and 4-6. The Examiner has relied upon the Kedem et al. reference for the alleged teaching of "use of heat-sealed anion-exchange membrane & cation-exchange membrane bags see col. 1 line 35 - col. 2 line 26." In light of this alleged teaching, the Examiner has taken the position that it would be obvious to modify the Matsumura et al. device by providing the bag of Matsumura et al. with a dual sided ion-exchange membrane bag.

Applicants must respectfully disagree with this ground of rejection. Kedem et al. teach a bag made up of an anion-exchange membrane and a cation-exchange membrane. However, the bag is

filled with an electrolyte and is used for a de-salting device for electrophoresis. The bag of Kedem et al. is not filled with a medication nor is it used for an iontophoresis device. Additionally, neither of the membranes forming the bag of Kedem et al. employs a cross-linked ion-exchange resin as required in independent Claim 1.

According to Kedem et al., as well understood from the examples disclosed therein, the cation-exchange membrane is prepared by introducing sulphonic acid groups into the central portion of a polyethylene film for a like film by photosulphenation, and the anion-exchange membrane is prepared by treating the central portion of the cation-exchange membrane with a diamine to turn it into a quaternary ammonium. The bag for electrophoresis is obtained by heat sealing together the peripheral edges of the cation-exchange membrane and the anion-exchange membrane prepared by the disclosed method. However, the cross-link structure has not been introduced into either the cation-exchange membrane nor the anion-exchange membrane through practice of that method.

To introduce the cross-link structure, it would be necessary to execute a reaction by using a polyfunctional monomer or a peroxide as a matter of course. Kedem et al. fail to teach or suggest such use of such a reaction. Thus, it is clear to one of ordinary skill in the art that the ion-exchange membrane forming

the bag of Kedem et al. does not include the cross-link ion exchange resin of the present invention as claimed.

Moreover, for the reasons set forth above including the lack on the part of Kedem et al. of any teaching of use of cross-link ion-exchange resin, it is clear that the bag of Kedem et al. is not used in the field of iontophoresis with sealing of the medication contained therein. Thus, it is not seen how Kedem et al. can be combined with Matsumura et al. under 35 U.S.C. 103 to meet the terms of the claims as previously presented. Such a rejection requires the hindsight reconstruction of the prior art in light of Applicants' own disclosure. The Examiner has taken Applicants' own disclosure and has used it as a blueprint for piecing together various portions of separate prior art references in order to construct a ground of rejection purporting to meet the terms of the claims. Such a practice is forbidden in patent law and use of that practice makes it clear that the ground of rejection is untenable under 35 U.S.C. 103. *Heidelberger Druckmachinag v. Hantscho Commercial Products, Inc.*, 21 F.3d 1060, 1072, 30 USPQ 2d 1377-1379-80 (Fed. Cir. 1994).

For the reasons set forth above, it is respectfully submitted that the claims as now presented patentably distinguish from the prior art applied thereagainst in the outstanding Office Action.

In that Office Action, the Examiner provides a response to arguments filed January 31, 2007. The Examiner has alleged that the fact that Matsumura et al. do not describe or suggest sealing an ionic medicine in a bag is "moot" since the Examiner has relied upon the teachings of Sibalis and Kedem et al. for that feature. For the reasons set forth above, with all due respect, the teachings of Sibalis and Kedem et al. are not combinable with the teachings of Matsumura et al. concerning the structure of the bag because those teachings would not result in a bag permitting ionic exchange. The Examiner has indicated that the Matsumura et al. reference discloses the porosity of the membranes to the range claimed by Applicants. Even if this were true, the other distinctions described above between the claims and the teachings of Matsumura et al. and the secondary references have not been overcome in the outstanding Office Action.

Moreover, the Examiner has argued that the Kedem et al. reference "is only utilized for the teachings of the bag." This reliance solely upon the bag of Kedem et al. is strong evidence of picking and choosing features from prior art references and combining them together using Applicants' own disclosure as a blueprint to do so, a practice forbidden in patent law. *Heidelberger Druckmachinag.*

For these additional reasons, it is respectfully submitted that the present invention as now claimed patentably distinguishes from the prior art applied thereagainst.

Although this Amendment is presented after a Final rejection, it is respectfully submitted that it should be entered and the application should be allowed as a result. The Amendment reduces the issues that would be present on Appeal by making a two word amendment to independent Claim 1 that overcomes the rejection of the claims under 35 U.S.C. 112, second paragraph. Applicants submit that this Amendment is merely of a clarifying nature and, technically, the claims as previously presented were fully definite under the purview of 35 U.S.C. 112, second paragraph. However, to satisfy the Examiner's concern, this Amendment has been presented to make it completely clear that which Applicants regard as the invention.

Moreover, the Amendment to overcome the rejection under 35 U.S.C. 112, second paragraph, is the only amendment presented herein. The claims are in essentially the same form at which they were presented previously and the arguments set forth herein make it plain that the grounds of rejection are untenable.

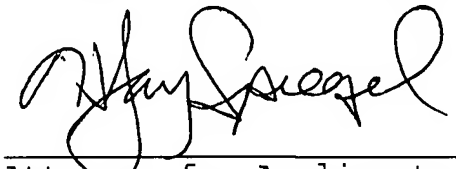
As such, the Examiner would not be required to make a further search or give additional comprehensive consideration in deciding whether the application should be allowed. Accordingly, even if the Examiner believes that the claims are not patentable,

given the reduction of issues that would be present on Appeal, it is respectfully submitted that the Amendment should be entered anyway along with an indication that the ground of rejection under 35 U.S.C. 112, second paragraph, has been withdrawn.

Accordingly, entry of this Amendment, reconsideration and allowance of the application are respectfully solicited.

Respectfully submitted,

H. JAY SPIEGEL & ASSOCIATES



Attorney for Applicants
H. Jay Spiegel
Reg. No. 30,722

H. JAY SPIEGEL & ASSOCIATES
P.O. Box 11
Mount Vernon, VA 22121
(703) 619-0101 - Phone
(703) 619-0110 - Facsimile
jayspiegel@aol.com - e-mail